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PATENT APPLICATION

**RESPONSE UNDER 37 CFR §1.116
EXPEDITED PROCEDURE
TECHNOLOGY CENTER ART UNIT 3739**

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of

Francis AMOAH

Group Art Unit: 3739

Application No.: 10/727,618

Examiner: R. Rollins

Filed: December 5, 2003

Docket No.: 114975

For: ELECTROSURGICAL METHOD AND APPARATUS

REQUEST FOR RECONSIDERATION UNDER 37 C.F.R. §1.116

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In reply to the January 26, 2005, Office Action, and the interview held March 23, 2005, reconsideration of the application is respectfully requested.

Claims 1, 3-6 and 8-22 are pending.

Applicant appreciates the courtesies shown to Applicant's representative by Examiner Rollins in the March 23, 2005 personal interview. Applicant's separate record of the substance of the interview is incorporated into the following remarks.

On page 2 of the Office Action, claims 1-22 were rejected under 35 U.S.C. §102(b) being anticipated by Stern et al., U.S. Patent No. 5,755,715 (Stern). As claims 2 and 7 have been cancelled, the rejection does apply. As to claims 1, 3-6 and 8-22, the rejection is respectfully traversed.

Applicant's apparatus of claim 1 includes a probe, the temperature of the probe is ramped up to a first equilibration temperature, the temperature of the probe is held substantially constant at the equilibration temperature for a period of time to allow the temperature of different parts of the probe to equilibrate, and the temperature of the probe is then increased to and maintained at a final steady state temperature, wherein the equilibration temperature is between 90°C and 105°C. Claim 6 is directed to a method in which the temperature of the probe is raised rapidly to a first threshold temperature, in a second equilibrating phase, the temperature of the probe is held substantially constant for a time period to allow the temperature of different parts of the probe to equilibrate, and in a subsequent treatment phase, the temperature of the probe is raised to a second, higher threshold temperature. . . wherein the first threshold temperature is between 90°C and 105°C.

Applicant's claim 13 is again directed to an apparatus including a probe, the temperature of the probe is ramped up to a first equilibration temperature, the temperature of the probe is held substantially constant at the equilibration temperature for a period of time to allow the temperature of different parts of the probe to equilibrate, and the temperature of the probe is then increased to and maintained at a final steady state temperature, wherein the final steady state temperature is between 100°C and 115°C. Claim 17 is directed to a method in which in an initial ramp-up phase, the temperature of the probe is raised rapidly to a first threshold temperature, in a second equilibrating phase, the temperature of the probe is held substantially constant for a period of time to allow the temperature of different parts of the probe to equilibrate, and in a subsequent treatment phase, the temperature of the probe is raised to a second, higher threshold temperature such that a lesion is formed in the tissue adjacent the probe without the complete removal of electrolytes in the tissue adjacent to the probe through vaporization, wherein the second threshold temperature is between 100°C and 115°C. Stern discloses no such thing.

In responding to the arguments presented in Applicant's November 9 filed Amendment, the Office alleges that Stern discloses steps of initially ramping the temperature of the probe up, holding the temperature constant for a period of time and then increasing the temperature as illustrated in Fig. 6B. The Office Action then goes on to allege that because Stern discloses the same method steps, it inherently performs the same function. Lastly, the Office Action alleges the temperature value disclosed by Stern is based on what the physician wants to maintain at the ablation site, and that, as illustrated in Fig. 1, the temperature can be between 20 and 120°.

Such totally misconstrues the entire teaching of Stern. First, Stern is substantially the related art discussed in Applicant's Background of the Invention. In that discussion, Applicant notes that it is well known that to produce a lesion the temperature of the tissue should be kept below 100°C, the temperatures above 100°C are known to cause charring and desiccation of the tissue. Applicant specifically notes that the prior art teaches the temperatures in a range of 80° to 100°C for ablation, or lesion creation, are typical for this type of apparatus. Stern falls within that category.

Although the dial shown on the display, or the interface, 66 is graduated between 20 and 120°, Stern specifically teaches setting a temperature in a range of 50 to 90°C (col. 6, line 14; col. 10, line 10). Further, Stern says that the temperature will preferably be 70°C (col. 10, line 11). Stern goes on to say that in a case of cardiac ablation, the maximum temperature is believed to lie in the range between 80°C and 95°C with a preferred representative value of about 90°C (col. 16, lines 29 and 30). Lastly, Stern emphasizes that if the power is applied to heat the tissue too quickly, the actual maximum tissue temperature in the region may exceed 100°C, and that would lead to tissue desiccation (col. 11, lines 61-64) which clearly implies that it is the goal of Stern to maintain the temperature below 100°C.

Further, Figs. 6A and 6B of Stern show how the set temperature is reached. Fig. 6A is substantially a linear function until approaching the desired or set temperature, when it becomes a nonlinear function as the slope flattens out to reach the temperature or final control value for ablation (col. 9, lines 55-62). Fig. 6B is an alternative implementation. In the alternative implementation, the temperature is raised in two steps. Step 1, from $t=0$ to $t=2$ seconds, the value of T_{set} progressively increases in a straight line with a selected slope and then, starting at $t=3$ seconds, the slope begins to be expressed in terms of a nonlinear function where it flattens out to a first preselected value for thermal mapping. The value for thermal mapping is within a range of 45 to 50°C. Then, at about $t=10$ seconds, T_{set} again progressively increases as a straight line with a selected slope until about $t=13$ seconds when it becomes a nonlinear function and flattens out to approach a second preselected value for tissue ablation. The second value is within the range 50°C to 90°C and preferably is about 70°C (col. 9, line 63 – col. 10, line 12). Thus, Stern substantially complies with Applicant's Description of Related Art in his control of temperatures.

In particular, Stern's first value of Fig. 6B, which the Office Action alleges is an equilibration temperature, although Stern calls it a thermal mapping temperature, is well below Applicant's equilibration temperature (claim 1) or first threshold temperature (claim 6). Stern's tissue ablation temperature is also well below Applicant's first steady state temperature (claim 13) or second threshold temperature (claim 17).

Further, by first stopping the temperature increase (for thermal mapping) at such a low point, so far removed from the ablation point, it does not appear to be an effort to equilibrate, or obtain a substantially uniform temperature throughout, the entire probe. Based on the terminology one might surmise that the thermal mapping is to ensure that, based upon the current provided, the temperature is rising appropriately so that once current is applied for ablation one can project an accurate temperature. In any case, neither temperature range

meets Applicant's claimed temperature ranges. Even Stern's highest temperature range does not overlap Applicant's lowest temperature range other than at one point 90°C , or 90-95°C for cardiac ablation, and Stern goes on to state that it is preferable that the temperature be about 70°C for ablation or 90°C for cardiac ablation. However, all those temperatures are in Applicant's equilibration zone, not the lesion forming (treatment) zone. Further Stern's Figs. 6A and 6B do not show reaching such temperatures, the graphs leveling off in the high 70's or mid 80's. Thus there is nothing in Stern that comes close to suggesting Applicant's claimed invention.

As noted, even when discussing cardiac ablation, using the highest temperatures, Stern maintains the maximum values of the temperature below Applicant's steady state or second threshold temperature range and its preferred value is at the lower end of Applicant's equilibration or first threshold temperature range. This clearly points out the distinction that Applicant has discovered that ablation or lesion formation can be done at temperatures previously thought to cause charring and desiccation, the very problem that Stern avoids by maintaining temperatures below 100°C. As such, Stern being substantially the related art suffers all the problems of the related art and, in fact, teaches away from Applicant's claimed invention.

Further, Stern clearly does not anticipate or suggest the subject matter of at least claims 3-5, 8, 11, 12, 14-16, 18, 19 and 22 dealing with various temperatures for the same reasons discussed above, and claims 9, 10, 20 and 21 for all the reasons discussed with respect to the claim from which they depend and for the additional features recited therein.

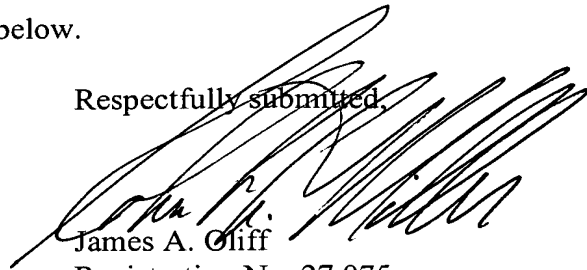
At the interview, the Examiner alleged that Stern inherently had the capability of operating as does Applicant's claimed invention. As Applicant's representative pointed out, in theory, a school bus can travel over 100 mph. However, most school buses are equipped with a governor to limit their speeds. Thus, although it may be asserted Stern has the capability to

operate in a manner similar to Applicant's apparatus, in fact, Stern does not. Stern teaches that the set temperature value T_{SET} represents the temperature the physician wants to maintain at the ablation site. Typically the temperature T_{SET} is in the range of 50°-90° C (column 6, lines 1-14). Thus, Stern's device has a governor built into it in the controller. Applicant's invention also has a controller that operates in a totally different way. The controllers are structural and, as defined by the U.S. Patent and Trademark Office, any programs or operating instructions embedded in such a structure are, in fact, structural/functional limitations on the apparatus. As a result, all of the arguments presented above concerning Stern and temperatures used are, in fact, structural/functional limitations on his apparatus as are those claimed.

In view of the foregoing, it is respectfully submitted that this application is in condition for allowance. Favorable reconsideration and prompt allowance of claims 1, 3-6 and 8-22 are earnestly solicited.

Should the Examiner believe that anything further would be desirable in order to place this application in even better condition for allowance, the Examiner is invited to contact the undersigned at the telephone number set forth below.

Respectfully submitted,



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